Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

The effect of family-centered empowerment model (FCEM) on the coping strategies of parents of children with cystic fibrosis

Protocol summary

Study aim
Determining the effect of family-centered empowerment model on coping strategies of parents of children with cystic fibrosis

Design
Clinical trial with control group

Settings and conduct
The study includes two groups of intervention and control. The intervention group in the family-centered empowerment project will use the family-based empowerment model to examine the impact of the model on parenting coping strategies. This template will be presented in four steps: perceived threat, increased self-efficacy, increased self-esteem and process evaluation, and six educational sessions will be provided for 6 weeks at the Cystic Fibrosis Clinic of the Children's Medical Center. Before the intervention and one month after it is completed, parents will be asked to complete the coping strategies questionnaire. In the control group the training will not be given. The parents of this group are requested to complete the questionnaire two months after completion of the coping strategies.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Passed at least six months from the diagnosis of childhood cystic fibrosis, Having the least literacy of parents to read and write,The child has a medical record in the clinic. Exclusion criteria: The child is involved in other chronic illness, in addition to cystic fibrosis, the occurrence of any unexpected incident affecting life from two months before entering the study,Parental involvement in physical and psychological illness.

Intervention groups
In intervention group (one group), family-centered empowerment model in four steps including perceived threat, increasing self-efficacy in child care, increasing self-esteem in child care and process evaluation in six training sessions from 20 to 40 minutes for 6 week will be held. The control group receives the routine training.

Main outcome variables
Coping Strategies score in Lazarus Questionnaire

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20180501039489N2**
Registration date: **2019-01-09, 1397/10/19**
Registration timing: **prospective**

Last update: **2019-01-09, 1397/10/19**
Update count: **0**

Registration date
2019-01-09, 1397/10/19

Registrant information

Name
Fahimeh Sabeti

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 21 8888 2885

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-01-10, 1397/10/20

Expected recruitment end date
2019-05-10, 1398/02/20

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The effect of family-centered empowerment model (FCEM) on the coping strategies of parents of children with cystic fibrosis

Public title
The effect of family empowerment on the coping strategies of parents of children with cystic fibrosis

Purpose
Education/Guidance

Inclusion/Exclusion criteria
Inclusion criteria:
Passed at Least Six Months of Diagnosis of Childhood Cystic Fibrosis parents' low literacy The Child has a Medical Record in the Clinic
Exclusion criteria:
The child is involved in other chronic illness, in addition to cystic fibrosis The occurrence of any unexpected incident affecting life from two months before entering the study Parental involvement in physical and psychological illness

Age
No age limit

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **78**

Randomization (investigator's opinion)
Not randomized

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Iran University of Medical Sciences
Street address
Iran University of Medical Sciences, Shahid Hemmat Highway, Tehran, 1449614535, IRAN
City
Tehran
Province
Tehran
Postal code
1449614535

Approval date
2018-09-03, 1397/06/12

Ethics committee reference number
IR.IUMS.REC.1397.187

Health conditions studied

1

Description of health condition studied
Cystic Fibrosis

ICD-10 code
E84

ICD-10 code description
Cystic fibrosis

Primary outcomes

1

Description
Coping Strategies score in Lazarus Questionnaire

Timepoint
before the intervention and one month after the end of empowerment training

Method of measurement
Lazarus Folkman Coping Strategies Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: After completing the coping strategies questionnaire and demographic information, parents of children referred to the cystic fibrosis clinic in the parental intervention group will be included in the family-centered empowerment design using the family-centered empowerment model of Dr. Alhani. This pattern is based on four steps: perceived threats including perceived severity and perceived sensitivity, increased self-efficacy, increased self-esteem and process evaluation, and by holding six training sessions of 20 to 40 minutes on Thursdays at the Cystic Fibrosis clinic of Medical Center will be provided. Meetings will be held in groups of 4 to 6 for parents. One month after the completion of the empowerment plan, parents will be asked to complete the coping strategies questionnaire.

Category
Prevention

2

Description
Control group: Parents referring to the cystic fibrosis clinic of the Children's Medical Center Hospital in the control group will be provided with demographic information and coping strategies. Once completed, parents will routinely take care of their children. Two months after the completion of the questionnaire, Parents will be asked to complete the coping strategies questionnaire.

Category
Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center
Cystic Fibrosis Clinic, Children's Medical Center Hospital, Tehran, Iran

Full name of responsible person
Somayeh Kiani

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Children's Medical Center, Qarib St, Keshavarz Blvd

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Web page address

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Iran University of Medical Sciences

Full name of responsible person
Seyyed Kazem Malekoti

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malakoutik@yahoo.com

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Iran University of Medical Sciences

Proportion provided by this source
100

Public or private sector
Public

Domestic or foreign origin
Domestic

Category of foreign source of funding
empty

Country of origin

Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact

Name of organization / entity
Iran University of Medical Sciences

Full name of responsible person
Fahimeh Sabeti

Position
Instructor

Latest degree
Master

Other areas of specialty/work
Nursery

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Person responsible for scientific inquiries

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Faculty member

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available